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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/980,038	11/26/97	KAUFMAN R	21150011184US

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EXAMINER	
CELSA, B	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 09/30/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

1- File Copy

File copy

Office Action Summary

Application No.	Applicant(s)
08/980,038	Kaufman et al.
Examiner	**Group Art Unit**
Bennett Celsa	1654

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-9 and 17-101* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-9 and 17-101* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claims 1-9 and 17-101 are currently pending. Claims 10-16 were canceled by preliminary amendment and new claims 41-101 were added.

The present application is a continuation application (and not a 371) of PCT/US97/06563, since the prerequisites for filing under 35 USC 371 were not met.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4 and 8, drawn to a 309 modified FVIII analog proteins and pharmaceuticals thereof, classified in class 514 and 530, subclasses 2+ and 350+, respectively.

II. Claims 5-7 and 9, drawn to a recombinant method of making Group I proteins, classified in class 435, subclass 69.1+.

III. Claims 17, 20-23 and 27, drawn to a B/VW/ 740 and A2/A3 spacer FVIII protein analog and pharmaceutical thereof classified in classes 514 and 530, subclass 2+ and 350+, respectively.

IV. Claims 24-26 and 28, drawn to a recombinant method of making Group III proteins, classified in class 435, subclass 69.1+.

V. Claims 29-31, drawn to a method of increasing the binding of a Group III protein in plasma using an antibody, classified in class 424, subclass 130.1+..

VI. Claims 32 and 36, drawn to a thrombin activated factor VIII heterodimer protein and a pharmaceutical thereof, classified in class 514 and 530, subclasses 2+ and 350+, respectively.

VII.. Claims 33-35 and 37, drawn to a recombinant method of making the Group VI proteins, classified in class 435, subclass 69.1+.

VIII. Claims 38-40, drawn to a method of increasing the binding of a Group VI protein using an antibody, classified in class 424, subclass 130.1+..

IX.. Claims 41-44 and 48, drawn to a 309/336/562 factor FVIII analog protein, classified in class 514 and 530, subclasses 2+ and 350+, respectively.

X.. Claims 45-47 and 49, drawn to a recombinant method of making a Group IX protein, classified in class 435, subclass 69.1+..

XI.. Claims 18, 50-54 and 58, drawn to a B/VW/336/562/740 and A2/A3 spacer FVIII protein analog , classified in classes 514 and 530, subclass 2+ and 350+, respectively.

XII.. Claims 55-57 and 59, drawn to a recombinant method of making a Group XI protein, classified in class 435, subclass 69.1+.

XIII.. Claims 60-62, drawn to a method of increasing Group XII binding using an antibody, classified in class 424, subclass 130.1+

XIV.. Claims 19, ~~63-67~~ and ~~71~~, drawn to a B/VW/309/740 and A2/A3 spacer FVIII protein analog and a pharmaceutical composition thereof, classified in classes 514 and 530, subclass 2+ and 350+, respectively.

~~XV~~.. Claims 68-70 and 72, drawn to a recombinant method of making a Group XIV protein, classified in class 435, subclass 69.1+.

~~XVI~~.. Claims 73-75, drawn to a method of increasing the binding of a Group XIV protein using an antibody, classified in class 424, subclass 130.1+..

~~XVII~~. Claims 76-80, 84 and 90, drawn to a B/VW/309/336/562/740 and A2/A3 spacer FVIII protein analog and a pharmaceutical composition thereof, classified in classes 514 and 530, subclass 2+ and 350+, respectively.

~~XVIII~~. Claims 81-83 and 85, drawn to a recombinant method of making Group XVII proteins, classified in class 435, subclass 69.1+.

~~XIX~~. Claims 86-88, drawn to a method of increasing the binding of a Group XVIII protein using an antibody, classified in class 424, subclass 130.1+.

~~XX~~. Claims 89, 91-94, 98, 100 and 101 drawn to a B/VW/336/562/740 and A2/A3 spacer FVIII protein analog/antibody conjugate and a pharmaceutical composition thereof, classified in classes 424 subclass 130.1+.

~~XXI~~. Claims 95-97 and 99, drawn to a recombinant method of making a Group XX protein, classified in class 435, subclass 69.1+..

2. The inventions are distinct, each from the other because of the following reasons: Inventions (I and II) and (III and IV) and (VI and VII) and (IX and X) and (XI and XII) and (XIV and XV) and (XVII and XVIII) and (XX and XXI) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products as claimed can be made by another and materially different process such as by solid or liquid phase peptide syntheses.

3. The protein compounds of Groups I, III, VI, IX, XI, XIV, XVII and XX are directed to patentably distinct proteins due to differences in structure including, but not limited to, differences in amino acid content and/or length and/or the presence of nonconservative substitutions and/or deletions and/or differences in secondary structure (e.g. cyclic) and/or the presence of an antibody conjugate; and further expected differences in physicochemical properties resulting from structural differences and/or differences in method of manufacture e.g. by use of different recombinant constructs. Further, the amino sequence searches of relevant databases as well as bibliographic searches of the proteins within the above groups is necessarily different and individually burdensome due to the divergent nature of each Group search.

4. The recombinant methods of Groups II, IV, VII, X, XII, XV, XVIII and XXI represent patentably distinct methods since each method is directed to the syntheses of a different protein and further requires unique recombinant constructs (e.g. vectors, plasmid, hosts etc). The

differences among the methods of the different groups would necessitate different and individually burdensome bibliographic and sequences searches for each method

5. The methods of increasing the binding of different proteins utilizing an antibody in Groups V, VIII, XIII, XVI, and XIX are patentably distinct due to differences in the method objectives and/or expected generic differences in antibody specificity and other physicochemical properties..

6. Because these inventions are distinct for the reasons given above and:

a. have acquired a separate status in the art as shown by their different classification;

b. require separate literature and/or sequence searches; and

c. because of their recognized divergent subject matter; restriction for examination purposes as indicated is proper.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (703)308-0254.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa

BC

September 29, 1998